

United States Senate

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Grassley, Breaux Seek Answers on Chemical Restraint Guidelines for Nursing Homes

WASHINGTON -- Sen. Chuck Grassley, ranking member of the Committee on Finance, and Sen. John Breaux, chairman of the Special Committee on Aging, are asking government officials to clarify draft guidelines that could lead to greater use of anti-psychotic medications that act as chemical restraints in nursing homes. The draft guidelines came from the previous presidential administration. Breaux and Grassley are seeking an update from the current administration.

Breaux said, "While recent studies have shown a dramatic reduction in the use of chemical restraints in institutions, these new draft guidelines leave open the possibility of reversing that trend. We have been working for years to reduce usage of chemical restraints, but the new draft guidelines are muddled enough to allow nursing homes to fall back into old habits of dependency on these drugs. We must ensure these guidelines are clear for the nursing home operators who use them, and that these guidelines continue to discourage the use of chemical restraints, whenever possible."

Grassley said, "Congress clearly intended to minimize the use of chemical restraints to control nursing home residents the last time we passed a law on the subject. Draft guidelines for implementing that law seem to offer room for the potentially inappropriate use of anti-psychotic medications to restrain nursing home residents. We need to reconcile this conflict. First, we have to make sure the guidelines match congressional intent. Second, although studies show substantial reductions in the use of chemical restraints in recent years, we nevertheless have to prevent any backslide to the bad old days of widespread sedation in nursing homes."

The text of the senators' Sept. 9 letter to the administrator of the Centers for Medicare and Medicaid Services follows.

September 9, 2002

The Honorable Thomas Scully
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

Dear Mr. Scully:

We are writing to renew our inquiry about the status of the draft Guidelines respecting the use of chemical restraints in nursing homes that Acting Administrator Hash sent to us with his letter of December 7, 2001. We apologize for the long delay in renewing our correspondence on this matter.

Since we have not received a copy of final Guidelines, we assume that none have yet been issued. Our staff's inquiries support that assumption. If we are mistaken, we would appreciate receiving a copy of the new Guidelines. If we are correct, we now respond to Mr. Hash's invitation for comments upon the draft Guidelines.

As your files will reflect, the correspondence that led to the drafting of revised Guidelines began several years ago with our letter of September 8, 1997, to the Administrator. Our concern was whether the Guidelines respecting chemical restraints conform to the statutory prescription that such restraints be used "only" where there is a threat to "physical safety" (Section 4201(c)(A)(ii) of the Omnibus Budget Reconciliation Act of 1987). The Guidelines, in permitting the use of anti-psychotic drugs to stop persons suffering from dementia or Alzheimers Disease from "scream[ing], yell[ing], or pac[ing]" even where there is no threat to "physical safety" appeared to be in tension with the statute. See Guidelines TAG Numbers F330 and F331. Our purpose in pursuing this matter through the exchange of a number of letters, as well as through discussions between our two staffs, was to secure the agency's views as to how the Guidelines and statute can be reconciled and whether modification of the Guidelines would be desirable in order to ensure statutory compliance.

We are encouraged by the general emphasis in the draft Guidelines upon the essentiality of restricting the use of anti-psychotic drugs to situations in which they are the only reasonable alternative. But we are uncertain how the specific Guideline provisions in question, as revised, materially change the current situation. We are especially interested in securing an explanation of what seems to be a significant difference between the draft Guidelines and the Acting Administrator's description in his December 7th letter of situations in which anti-psychotic drugs may properly be used. Accordingly, we would appreciate your responses to several questions that we have framed in order to identify with some precision the points upon which we are in doubt. Those questions are as follows:

1. In his letter of December 7th, Mr. Hash repeated the basic position of HCFA, as we understand it, that "[w]here drugs are properly used to treat a resident's medical symptoms, they do not trigger the restraint provisions of the statute . . ." (letter p. 1). In further specification of this general proposition, he described the conditions that "should be met" to warrant this use of anti-psychotic drugs in order to control certain "behaviors." Those conditions include the requirement that the behaviors "are impairing, or having a high likelihood of impairing, personal functioning to the extent of presenting a major disruption, or significant risk of such disruption [,] to the individual's life, health, or safety or the life, health or safety of others." Thus, even though the drug is being employed to restrain behavior and might be thought therefore to fall within the statutory prohibition, we understood HCFA to maintain that the prohibition should not apply where the ultimate purpose is to deal with a "major" threat to life, health, or safety.

Assuming this to be a reasonable view of the statute, the problem posed by the draft Guideline is that the word "major" has been dropped, so that there need be only "a danger to the individual's life, health or safety or the life, health or safety of others."

Our first question, then, is why the term "major" was dropped. The omission appears to make a critical difference, particularly in view of the examples that are provided, which we discuss next.

2. The draft Guidelines provide several "[e]xamples of chronic behaviors that would reflect such impairments of functioning." The first of these examples, "physical aggression," is related to

the statutory test of “physical safety.” The second example relates to the type of behavior that has been the focus of our correspondence. It concerns “screaming or yelling,” now more particularly defined in the draft as screaming or yelling “that disrupts the sleep of other residents or interferes with their ability to participate in or appreciate recreational activities.”

a. Please provide examples of interference with a patient’s “ability to participate in or appreciate recreational activities” that would constitute a “danger . . . to life, health or safety.” When, if ever, would such an interference constitute a “major” danger?

b. Cannot the draft reasonably be read to permit the use of anti-psychotic drugs to stop a patient from yelling or screaming if there is any significant interference with another patient’s sleep? How could such use of anti-psychotics be said to conform with the statute?

c. In these instances in which the focus is entirely upon the impact of the patient’s behavior upon others, would it be accurate to say that the drug is not being used to treat the patient’s mental condition but rather simply to control his behavior? To put it differently, in the absence of the behavior in question, would administration of the drug be considered medically appropriate and legally permissible? If not, where the impact on others does not constitute a threat to physical safety, how can it be said that such use of anti-psychotics conforms to the statute?

d. While we recognize the legitimate concern of nursing homes about socially undesirable behavior such as those types listed in the third set of examples (“socially inappropriate behaviors”), we assume that you will agree that compliance with the statute will generally require measures other than the use of anti-psychotic drugs to maintain an orderly and civil environment. As to the examples in the draft of “socially inappropriate behaviors” other than sexual advances and touching – i.e., urinating or defecating or disrobing – in what circumstances would they be a “danger to life, health, or safety”? What if the requirement were that they be a “major” danger?

We appreciate your agency’s efforts to address concerns about the use of anti-psychotic drugs, and we look forward to receiving your response. We would appreciate a response by October 4, 2002.

Sincerely,

John B. Breaux
Chairman
Special Committee on Aging

Charles E. Grassley
Ranking Member
Committee on Finance